Pfizer Announces Top-Line Results Of Final Two Pivotal Phase 3 Trials Of Tofacitinib (CP-690,550) In Patients With Active Rheumatoid Arthritis

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Detailed Results to Be Submitted to Future Scientific Meeting

(BUSINESS WIRE)--Pfizer Inc. announced today top-line results from the ORAL Standard (A3921064) and ORAL Step (A3921032) Phase 3 studies of tofacitinib (development code: CP-690,550), an investigational, novel, oral JAK inhibitor.

ORAL Standard is a completed twelve-month study in patients with moderate-to-severe active rheumatoid arthritis (RA) who had an inadequate response to methotrexate (MTX) and were randomized to receive tofacitinib 5 or 10 mg BID, adalimumab 40 mg subcutaneously every other week or placebo, each of which was added to stable background MTX.

The ORAL Standard study met all primary endpoints at the 5 and 10 mg BID doses of tofacitinib, showing statistically significant changes versus placebo in reducing signs and symptoms of RA, as measured by ACR20 response rates at six months; in improving physical function, as measured by mean change in HAQ DI at three months; and in reaching DAS28-4(ESR) <2.6 at six months.

ORAL Step is a completed six-month study in patients with moderate-to-severe active RA who had an inadequate response to a TNF inhibitor and were randomized to receive tofacitinib 5 or 10 mg BID or placebo, which were added to stable background MTX.

The ORAL Step study met all primary endpoints at the 5 and 10 mg BID doses, showing statistically significant changes versus placebo in reducing signs and symptoms of RA, as measured by ACR20 response rates; in improving physical function, as measured by mean change in HAQ DI; and in reaching DAS28-4(ESR) <2.6, all assessed at three months.

No new safety signals emerged in the ORAL Standard and ORAL Step studies. The efficacy and safety profile of tofacitinib in these studies remains consistent with that seen previously in the clinical program.

A detailed analysis of the ORAL Standard and ORAL Step efficacy and safety data, including secondary endpoints which are not reported here, will be submitted to a future scientific meeting.

About ORAL Standard (A3921064)

ORAL Standard is a twelve-month study that enrolled 717 patients with moderate-to-severe active RA who had an inadequate response to MTX to receive tofacitinib 5 or 10 mg BID or adalimumab 40 mg subcutaneously every other week or placebo, each of which was added to stable background MTX. Patients who had previously received adalimumab or had an inadequate response to a TNF inhibitor were excluded from participation. Patients were randomized such that at the month-three visit, nonresponding placebo-assigned patients were advanced in a blinded fashion to a predetermined treatment of tofacitinib, 5 or 10 mg BID, for the remainder of the study; at the end of six months, all placebo-assigned patients were advanced to their predetermined tofacitinib treatment assignment in a blinded fashion for the remainder of the study. Those patients assigned to 5 or 10 mg BID tofacitinib or adalimumab 40 mg every other week at the start of study remained on those dose regimens throughout the 12 months of the study.

About ORAL Step (A3921032)

ORAL Step is a six-month study that enrolled 399 patients with moderate-to-severe active RA who had an inadequate response to at least one TNF inhibitor to receive tofacitinib 5 or 10 mg BID or placebo added to stable background MTX. Those patients were randomized such that at the month-three visit, placebo-assigned patients were advanced in a blinded fashion to a predetermined treatment of tofacitinib, 5 or 10 mg BID, for the remainder of the study. Those patients assigned to 5 or 10 mg BID tofacitinib at the start of study remained on those dose regimens throughout the six months of the study.

About Rheumatoid Arthritis

Rheumatoid arthritis is a chronic inflammatory autoimmune disease that typically affects the hands and feet, although any joint lined by a synovial membrane may be affected. RA affects approximately 1.3 million people in the U.S. 1 and one percent of the adult population worldwide.2

About Tofacitinib

Tofacitinib is a novel, oral Janus kinase (JAK) inhibitor that is being investigated as a targeted immunomodulator and disease-modifying therapy for RA. More than 4,000 RA patients have been treated with tofacitinib in clinical trials to date. Unlike more recent therapies for RA, which are directed at extracellular targets such as pro-inflammatory cytokines, tofacitinib takes a novel approach, targeting the intracellular signaling pathways that operate as hubs in the inflammatory cytokine network.

Pfizer is studying tofacitinib for RA in the Phase 3 ORAL (Oral Rheumatoid Arthritis Phase 3 TriaLs) program, which consists of five pivotal trials and a sixth long-term treatment study at more than 350 locations in 35 countries worldwide. ORAL Standard and ORAL Step are the final two pivotal trials in the program.

Pfizer is also studying orally administered tofacitinib in psoriasis, inflammatory bowel disease (Crohn’s disease and ulcerative colitis) and renal transplant, and topical tofacitinib in both psoriasis and dry eye disease.

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DISCLOSURE NOTICE: The information contained in this release is as of April 28, 2011. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a product in development, tofacitinib, including its potential benefits as a treatment for rheumatoid arthritis, certain other diseases and renal transplant, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for tofacitinib as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and in its reports on Form 10-Q and Form 8-K.

1 Arthritis Today. "What is Rheumatoid Arthritis." Accessed 24 February 2011. Available at: http://www.arthritistoday.org/conditions/rheumatoid-arthritis/all-about-ra/what-is-ra.php.

2 Rubbert-Roth A, Finckh A. Treatment options in patients with rheumatoid arthritis failing initial TNF inhibitor therapy: a critical review. Arthritis Res Ther. 2009; 11(Suppl 1): S1.Published online 2009 April 6. doi: 10.1186/ar2662.

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